Section 6: 510(k) Summary

FEB 15 2013

510(k) Summary

Submitter's Information

Name	Renal Solutions, Inc.
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Official Contact	David J. Vanella Senior Vice President, Quality Assurance & Regulatory Affairs
Date Prepared	12/12/2012

Device Information

Name	2008 Sorbent System
Common/Usual Name	Hemodialysis System
Product Code	FKT
Classification Name	System, Dialysate Delivery, Sorbent Regenerated
Regulation Number	876.5600
Proprietary Name	2008 Sorbent System
Unmodified Device	2008 Sorbent System (K093362)
Reason for Submission	Modification to existing device

Device Description

The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician.

The 2008 Sorbent System consists of two distinct components:

- the 2008 Machine, and
- the SORB™ Module.

Section 6: 510(k) Summary

The SORB Module is a sorbent dialysate regenerative system that attaches to the 2008 Machine and replaces the machine's existing single-pass dialysate delivery system.

During treatment, used dialysate is chemically reprocessed into fresh, new dialysate and sent back to the dialyzer instead of being sent down a drain. By recirculating and regenerating the dialysate, the 2008 Sorbent System uses less than 15 liters of potable tap water per treatment compared to a standard single-pass system that uses at least 120 liters of purified water during a standard 4-hour dialysis treatment.

Intended Use

The intended use of the modified 2008 Sorbent System is identical to the unmodified device, 2008 Sorbent System (K093362).

Indications for Use

The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician.

Substantial Equivalence

The 2008 Sorbent System (K123835) is substantially equivalent to the unmodified device, 2008 Sorbent System (K093362), in terms of its intended use, environment of use, operating principles, and technology.

Renal Solutions has determined that the differences from the predicate device have no impact on the safety and effectiveness of the device and that the changes to the 2008 Sorbent System do not raise new types of safety or effectiveness questions. The design verification testing demonstrates the device meets the design requirements and supports substantial equivalence. In summary, the 2008 Sorbent Hemodialysis System (K123835) is substantially equivalent to the predicate device (K093362).

Area	Predicate	Modified Device
	2008 Sorbent System (K093362)	**2008 Sorbent System (K123835)**
Intended Use / Indications for Use	The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician.	Same
Target Population	Adults (≥ 18 years)	Same

Section 6: 510(k) Summary

Area	Predicate	Modified Device
	2008 Sorbent System (K093362)	**2008 Sorbent System (K123835)**
Environment of Use	Institutional, where competent intervention is present	Same
Energy Used and/or Delivered	• AC 120 V ± 10% • 60 Hz • 12.5 A max	Same
Treatment Duration	3 – 4 hours	Same
Sorbent Regenerative Model	Spent dialysate is passed through a sorbent cartridge and regenerated into fresh dialysate.	Same
Sorbent Cartridge Type	HISORB+TM Cartridge	Same
Sorbent Cartridge Layers	Layer 1: Activated Carbon Layer 2: Enzyme/Enzyme Retention Layer 3: Zirconium Phosphate Layer 4: Zirconium Oxide/Zirconium Carbonate	Layer 1: Activated Carbon Layer 2: Enzyme/Enzyme Retention Layer 3: Activated Carbon Layer 4: Zirconium Phosphate Layer 5: Zirconium Oxide/Zirconium Carbonate

2008 Sorbent System Verification (non-clinical) Testing Summary

The following list summarizes the 510(k) verification testing activities performed. These activities include performance and software testing, which demonstrates by technical examination that the 2008 Sorbent System meets its performance specifications and is substantially equivalent to the predicate device.

The following tests were conducted for the 2008 Sorbent System (K123835):

1. **2008 System Software/ Hardware**
   - 2008 Machine Functional SW Verification Protocol
   - Disinfection testing
   - Infusate Delivery testing
   - Modes of Operation testing
   - Alarms testing
2. **HISORB+ Cartridge**
   - Comparison of dialysate chemistries between a reconfigured HISORB+ cartridge and the HISORB+ cartridge
   - Modified HISORB+ cartridge performance testing
   - Modified HISORB+ cartridge shipping test

Section 6: 510(k) Summary

General Safety and Effectiveness

The modified 2008 Sorbent System (K123835) is an updated version of the 2008 Sorbent System (K093362). The performance and technological characteristics of the modified device are equivalent to those of the unmodified device and raise no new types of safety or effectiveness questions.

Conclusions

The verification (non-clinical) testing information consisting of performance and software testing that was performed verifies that the modified 2008 Sorbent System (K123835) meets its performance specifications and demonstrates that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

Renal Solutions, Inc.
% Mr. David J. Vanella
Senior Vice President Quality Assurance & Regulatory Affairs
770 Commonwealth Drive, Suite 101
WARRENDALE PA 15086

Re: K123835
Trade/Device Name: 2008 Sorbent System
Regulation Number: 21 CFR§ 876.5600
Regulation Name: Sorbent regenerated dialysate delivery system for hemodialysis
Regulatory Class: II
Product Code: FKT
Dated: January 18, 2013
Received: January 24, 2013

Dear Mr. Vanella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K123835

Device Name: 2008 Sorbent System

Indications for Use:

The 2008 Sorbent System is intended for adult acute and chronic uremic patients in the presence of a healthcare practitioner where hemodialysis is prescribed on the order of a physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number K123835